

Report

Global Recognition of Qualified Toxicologic Pathologists: Credential Review as a Potential Route for Recognizing the Proficiency of Pathologists Involved in Regulatory-type Nonclinical Studies*

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Abstract: Recent international summits of the International Federation of Societies of Toxicologic Pathologists (IFSTP) have debated the desirability and potential means by which the proficiency of an individual toxicologic pathologist might be recognized and communicated throughout the world. The present document describes the advantages and disadvantages of implementing such a global recognition system by any means, and provides a proposal whereby recognition might be accorded via rigorous credential review of a practitioner's education and experience. (J Toxicol Pathol 2009; 22: 143–152)

Key words: (Bench) toxicologic pathologists, education/training curriculum/standards, global recognition criteria, proficiency, international harmonization

Abbreviations

ABT	American Board of Toxicology
ABVT	American Board of Veterinary Toxicology
ACVP	American College of Veterinary Pathologists
BSTP	British Society of Toxicological Pathologists
CES	Certificat d'Etudes Supérieures [d'anatomie pathologique toxicologique] (Certificate of

CRP/TP	Advanced Studies in Toxicologic Pathology) Committee for the Registration of Laboratory Animal / Toxicological Pathologists in the Netherlands
DESV	Diplôme d'Etudes Spécialisées Vétérinaires [en anatomie pathologique vétérinaire] (Diploma of Specialization in Veterinary Pathology]
DU	Diplôme d'Université [d'anatomie pathologique appliquée à la toxicologie] (University Diploma in Toxicologic Veterinary Pathology]
ECVCP	European College of Veterinary Clinical Pathology
ECVP	European College of Veterinary Pathologists
EMA	European Medicines Agency
ERT	European Registered Toxicologist
ESTP	European Society of Toxicologic Pathology
FRCPath	Fellow of the Royal College of Pathologists (United Kingdom)
FTA Pathol	Fachtierarzt fuer Pathologie (Specialist for Veterinary Pathology)
FVH Pathol	FVH Spezialtierarzt fuer Pathologie (Foederatio veterinaria helvetiae - Federation of Swiss Veterinarians - Specialist for Veterinary Pathology)
IATP	International Academy of Toxicologic

*The content represents the views of toxicologic pathologists from three continents (Asia, Europe, and North America).

The document has been reviewed and is endorsed by the senior bodies of the IFSTP member societies representing Europe (ESTP) as well as the national societies of toxicologic pathology from France (SFPT), India (STP-I), Italy (SIPTS), Japan (JSTP), the Netherlands (NVT), South Korea (KSTP), and the United Kingdom (BSTP). The STP (representing North America) will discuss the paper and poll its membership on the desirability of such a mechanism at its annual meeting in Washington, D.C. during June, 2009.

As a service to their members, this document has been published concurrently in the scientific journals of the BSTP and STP (*Toxicologic Pathology*), ESTP (*Experimental and Toxicologic Pathology*), and JSTP (*Journal of Toxicologic Pathology*).

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	Pathology
IFSTP	International Federation of Societies of Toxicologic Pathologists
JCVF	Japanese College of Veterinary Pathology
JST	Japanese Society of Toxicology
JSTP	Japanese Society of Toxicologic Pathology
SFPT	Société Française de Pathologie Toxicologique (French Society of Toxicologic Pathology)
SIPTS	Società Italiana Patologica Tossicologica Sperimentale (Italian Society of Experimental Toxicologic Pathology)
STP	Society of Toxicologic Pathology (North America)
SVT	Schweizerische Vereinigung fuer Tierpathologie (Swiss Association of Veterinary Pathology)

Introduction

Toxicologic pathologists are involved in the evaluation of new products including chemicals, food components, agrochemicals, pharmaceuticals, and medical devices. Of particular importance in this process are broadly trained and experienced toxicologic “bench” pathologists responsible for the macroscopic and microscopic evaluation and interpretation of regulatory-type safety studies. Decisions by these pathologists may have a profound impact on human health. Their timely judgments may either permit valuable prospective compounds to progress through development or prevent possibly harmful substances from reaching the market. Consequences of inaccurate judgments may be magnified now that many products are marketed globally. The potential for a significant misjudgment to cause harm worldwide will be minimized if all practicing toxicologic pathologists involved in the evaluation of these regulatory safety studies are well-documented to have acquired a standard set of critical skills, knowledge, and experience. However, the truth of this premise is not immediately clear to lay individuals given the divergence in education and work experience among these pathologists in different nations.

Accordingly, a recent international summit of elected representatives from several societies of toxicologic pathology discussed the means by which the proficiency of an individual toxicologic pathologist¹ might be recognized and made known to employers, regulatory agencies, and health authorities throughout the world. The consensus reached during this session was communicated to the members of the participating societies in the form of a white paper (Ettlin *et al.*, 2007 / 2008), which was published concurrently in the scientific annals of the ESTP (*Experimental and Toxicologic Pathology*), the JSTP (*Journal of Toxicologic Pathology*), and the BSTP and STP (*Toxicology Pathology*).

The contents of this prior publication outlined several elements that should be considered when evaluating the proficiency of a toxicologic pathologist. The present

document extends the previous article by discussing the following proposition: “Assuming that the toxicologic pathology profession worldwide would benefit from a global system for recognizing the proficiency of individual pathologists, how might the global toxicologic pathology community proceed to implement such a process?” A global system for recognizing competence would need to be structured in such a manner that it would add substantial value for individual practitioners, and would also inspire confidence in their competence by employers, health authorities, regulatory agencies, and the general public.

Several essential questions must be contemplated when considering the value (or lack thereof) in such a global recognition system. These can be summarized in seven broad queries:

1. What are the global standards for recognizing a qualified toxicologic pathologist?
2. To what extent would a global recognition pathway substantially augment existing means of recognizing individual proficiency?
3. What kinds of recognition are currently available, and by what mechanism should global recognition be conferred?
4. What institution(s) should oversee the recognition process?
5. What methodology might be most suitable to global recognition of proficiency?
6. What criteria should be employed to assess whether or not an individual has attained sufficient proficiency to merit global recognition?
7. How would the institution executing global recognition ensure consistent practice across regions and time during the recognition process?

This paper will seek to provide preliminary answers for these questions. The authors hope that these remarks will serve as central points for ongoing discussion as the global toxicology pathology community evaluates the potential merits of an international recognition process for proficient pathologists.

What Are the Global Standards for Recognizing a Qualified Toxicologic Pathologist?

This question is simple to ask, but perhaps will be complex to define. What skills will receive global acceptance as prerequisites for proficiency? The logical criteria for making such value judgments include an individual’s education, work experience, and in some venues the successful completion of a relevant examination (Ettlin *et al.*, 2007/2008). However, at this time no formal international standard exists for assessing the proficiency of toxicologic pathologists.

The absence of a global benchmark for assessing proficiency reflects the breadth of duties undertaken by toxicologic pathologists. In some situations a qualified toxicologic pathologist will be the individual who can most accurately detect toxicant-induced changes in tissues or

other specimens from regulatory-type studies. In other settings the designation of “qualified” might only be accorded to a toxicologic pathologist who is sufficiently well versed in lesion identification and many related disciplines (pathophysiology, comparative medicine, pharmacodynamics and pharmacokinetics, metabolism, molecular biology, etc.) to be able to provide an integrated understanding of a lesion’s significance and a useful context for designing strategies to characterize and mitigate any problems they might represent. Therefore, the broadest statement of this question might be, “What is an acceptable balance between the theoretical and hands-on skills required in a competent toxicologic pathologist?” The answer to this query will likely dictate the best means of providing global recognition of proficiency going forward - credential review, examination, expanded peer review, or maintaining the status quo (based on existing national and regional credentialing processes as well as peer review). The international community of toxicologic pathologists must first determine the essential core skills of a qualified practitioner on a global level before a meaningful discussion of mechanisms for demonstrating proficiency can be undertaken. The current patchwork of national and regional certifying systems (whether by credential review or examination) supplemented by rigorous peer review and international outreach efforts to establish common educational and practice methods in toxicologic pathology should provide a reliable means of ensuring adequate proficiency of toxicologic pathologists throughout the globe. Addition of a global recognition mechanism to these existing criteria would provide a single, globally applicable document demonstrating an acceptable degree of proficiency.

To What Extent Would a Global Recognition Pathway Substantially Augment Existing Means of Recognizing Individual Proficiency?

Traditionally the decision regarding the basic proficiency of toxicologic pathologists has been a function of the employer’s needs and the individual’s performance, and not subject to oversight by national or regional health authorities or regulatory agencies. The current consensus among most clients for toxicologic pathology services (e.g., firms that develop medicinal or chemical products and/or medical devices, contract research organizations, health authorities, and regulatory agencies) is that present practices for recognizing the proficiency of individual practitioners, when coupled with the regular use of peer review by other experienced toxicologic pathologists, are capable of ensuring the proper acquisition and quality interpretation of toxicologic pathology data. However, regulatory guidelines requiring that pathology data be acquired and interpreted by a “qualified” pathologist (EMA, 2002; FDA, 2004) have, by not defining the attributes of a “qualified” individual, created ambiguity regarding if and how proficiency should be evaluated and documented. This requirement, coupled

with the existence of experienced practitioners in the field who lack any formal certification as pathologists, suggests that a worldwide benchmark for recognizing proficiency as a competent toxicologic pathologist would be beneficial.

Toxicologic pathologists utilize their unique training, experience and credentials to obtain employment in the field, even if they move abroad to practice. Regulatory agencies seldom dispute the ability of a toxicologic pathologist based on paper qualifications. Nevertheless, a formal, global system for recognizing proficiency in toxicologic pathology would offer many advantages to multiple constituencies, including toxicologic pathologists (both individually and collectively), their employers, and the entities that rely on their expertise (e.g., health authorities, regulatory agencies, academic institutions, and the general public). Prominent examples include:

- * Ready international recognition of qualified individuals,
- * Clear and consistent published criteria for recognizing “proficient” practitioners,
- * A well-defined system for recognizing those who do not currently have ready access to regional or national postgraduate certification schemes,
- * Improved global harmonization on standards for training future generations of toxicologic pathologists, and
- * Enhanced international employment opportunities.

In short, an effective international system for recognizing proficiency in toxicologic pathology could serve to both ease and speed the ongoing process of global integration that is a prominent practice of multi-national corporations in the 21st century.

What Kinds of Recognition Are Currently Available, and by What Mechanism Should Global Recognition Be Conferred?

This ostensibly straightforward topic is subject to considerable debate due to the divergence in existing national and regional practices for evaluating the proficiency of toxicologic pathologists. An international standard for recognizing the proficiency of toxicologic pathologists could take many forms. Logical choices would include documenting the successful completion of a core curriculum covering universally accepted knowledge in the field, increased use of pathology peer review (without respect to national borders), and/or a formal accrediting system based on either a formal examination or credential review. Some locales administer a formal certifying examination targeted specifically to the toxicologic pathology discipline (e.g., JSTP). Such tests directly assess whether or not a given individual has an essential core body of knowledge in the field. An alternative examination format in Germany provides a veterinary pathologist already certified as a diagnostician (FTA Pathol, granted by oral examination after a 5-year training program) an additional certificate in toxicologic pathology after 2 more years of training under an

experienced toxicologic pathologist and another oral examination. In contrast, toxicologic pathologists in the Netherlands and Switzerland are registered by the CRP/TP and the “Schweizerische Vereinigung fuer Tierpathologie” (SVT) by reviewing their toxicologic pathology credentials following the successful completion of a 4-year, on-the-job, individualized training program under the supervision of a previously recognized senior toxicologic pathologist; registrants are then reappraised at 5-year intervals to confirm that suitable continuing education and experience within the field have been maintained. Still other locales oversee thorough certifying examinations in general and veterinary anatomic and/or veterinary clinical pathology (e.g., ACVP, DESV [anatomic pathology], ECVP, ECVCP, and JCVP). Such examinations are designed to verify that sufficient theoretical and practical knowledge in veterinary diagnostic pathology has been gained in the course of a pathology training program to effectively perform pathology investigations. They are not intended to confirm that an individual has gained an understanding of the core knowledge specific to the toxicologic pathology field, though there might have been exposure to toxicologic pathology. Nevertheless, individuals who have completed such rigorous pathology examinations are usually regarded as able to apply their basic pathology skills to toxicologic pathology problems. All of these mechanisms have been considered fitting methods for assessing toxicologic pathologists, including those working in research, based on their successful use over years (e.g., ECVP) to decades (e.g., ACVP, CRP/TP, DESV, FRCPath, FTA Pathol, FHV Pathol, JCVP, and JSTP). The existence of comparable training opportunities in the past which have since disappeared must be taken into consideration when evaluating the educational qualifications of some older toxicologic pathologists (e.g., CES, DU).

The existing methods by which proficiency in toxicologic pathology is assessed in different parts of the world suggest that several potential points of contention might arise when considering a new global mechanism for recognizing competency in this discipline.

- * First, those scientists who have previously achieved recognition as proficient toxicologic pathologists using one of the means noted above will understandably be reluctant to undertake the effort needed to attain another credential. A feasible solution to this dilemma would be to recognize existing certifications, if they fulfill the criteria of the new global system.
- * Second, the implementation of a new global system for recognizing proficiency in toxicologic pathology might be perceived to devalue some of the existing national and regional pathways if, in the future, health authorities or regulatory agencies begin to only accept those data generated by practitioners holding a global credential. The authors believe this scenario to be unlikely, on the assumption that the existing national/regional schemes will provide an assessment of comparable rigor when compared to the international

mechanism.

- * The final point of conflict is likely to be agreement on a mechanism for conferring global recognition (see also section below “What methodology might be most suitable to global recognition of proficiency?”). Institutions that advocate certifying examinations contend that such tests provide a more rigorous, objective, and consistent appraisal of proficiency than would a simple review of documents detailing one’s education and experience. However, others assert that a suitable progression of educational opportunities and practical experience with direct bearing on the daily practice of toxicologic pathology has greater relevance than the successful conclusion of an exacting examination.

We anticipate that significant dialogue will be required within the international toxicologic pathology community before these conflicts can be resolved, even for such a seemingly worthy goal as creating a global recognition process to confirm that practitioners have the minimal educational requirements and experience needed to truly guard the public health.

What Institution(s) Should Oversee a Global Recognition Process?

The logical consequence of premise no. 3 above is that any global scheme for recognizing proficiency in toxicologic pathology should be administered by an entity with global reach rather than by a more localized body (e.g., such regional societies as the BSTP, ESTP, JSTP, or STP). Of course, these societies, and possibly other societies such as (veterinary) pathology societies at large, must be involved.

An existing global organization that might assume this role is the International Federation of Societies of Toxicologic Pathologists (IFSTP). This entity was founded by the respective national member societies in 1989 to - among other activities - promote the adoption of global standards for recognizing the capabilities of “qualified” toxicologic pathologists (IFSTP website); most STPs across the globe either belong to² or are seeking to join³ the IFSTP. One possible method by which the IFSTP could oversee this might be through the International Academy of Toxicologic Pathology (IATP), an IFSTP derivative organized in 1999 to recognize experts (designated IATP “Fellows”) in toxicologic pathology. The latter experts can either be broad based or be specialists in a dedicated field of toxicologic pathology i.e. this recognition is not necessarily overlapping with the skills required for the toxicologic pathologists/practitioners of regulatory-type nonclinical studies as discussed in this paper (see Note 1). Fellows of IATP are selected based on a point-driven review of documented professional credentials that emphasizes both longstanding educational accomplishments (theory) and experience (practice).

The main advantage of tasking the IATP with administering such a global recognition system is that the mandated worldwide focus of IATP would facilitate

standardizing the review process throughout the world. A mechanism would need to be fashioned by which the collective will of the member societies would have a means for overseeing the process; a likely means would be to place this responsibility with the IFSTP. A disadvantage of using the IATP for this purpose is the need to achieve consensus regarding an entirely new set of criteria against which proficiency in pathology might be measured; this requirement arises from the bias of the current Fellow criteria toward intellectual achievements (e.g., publication record, external presentations, etc.) rather than proven excellence at performing those laboratory ("bench") functions usually fulfilled by study toxicologic pathologists. Another potential disadvantage of using IATP in this role is that the sudden influx of applicants seeking global recognition could overwhelm the small size of the IATP credentialing committee. This objection could be met by expanding the existing IATP committee with IFSTP-appointed representatives, or better yet by forming a new IATP committee to specifically address this new mandate.

An alternative approach might be for the IFSTP to moderate negotiations among its member societies to establish a minimum standard for proficiency in toxicologic pathology, after which the member societies would fashion means for their own constituents to meet that standard (either with or without IFSTP oversight). We predict that this latter option will prove untenable given the desire of individual societies of toxicologic pathology to maintain their traditional independence, which would likely preclude the adoption of a standard recognition system across all organizations.

A third option might be for the IFSTP and/or the IATP to assume a new responsibility as the oversight body tasked with sanctioning the certifying programs administered by the national and regional societies. This alternative is feasible in principle as the IFSTP has been engaged in efforts to recognize qualified toxicologic pathologists since its inception (e.g., IFSTP, 2003). Such an initiative would be particularly important, for future programs that will arise in developing countries which currently lack a long tradition of toxicologic pathology within their borders. Once again, however, we predict that this alternative will be untenable, for three key reasons. First, such an authority does not currently fall within the mandate of the IFSTP (a confederation of societies of toxicological pathology to build new societies, support the member organizations by integration and coordination of international activities and initiatives, and to set standards in toxicological pathology) or the IATP (a small group which recognizes individual expertise and also promotes education). Second, implementing this practice would require more resources than could be marshaled given the existing administrative machineries of the IATP and the IFSTP. Finally, in many venues the certifying procedures for those engaged in toxicologic pathology are not governed by the national or regional STP but rather by another body, which might understandably resent any effort to impose an external

control on its activities. The IFSTP and/or IATP might reasonably be expected to provide both information and experienced mentors to aid new national societies in developing rigorous credentialing programs.

The discussion among representatives of the member societies present at the Fall 2008 IFSTP Executive Committee meeting (September 24, in Edinburgh, Scotland) revealed a consensus favoring joint IFSTP / IATP participation in any future global recognition system for toxicologic pathologists whose primary focus is macro- and microscopic pathology of regulatory-type nonclinical safety studies. The delegates felt that the IFSTP should take the lead in coordinating debate among the member societies regarding the proper design of a global recognition process (albeit with input from IATP), while the IATP would be expected to direct assessment of the applications (possibly with assistance from IFSTP representatives). This arrangement would take maximal advantage of the existing international institutions and recognition machinery, thereby expediting the evolution of a global system for recognizing the proficiency of toxicologic anatomic pathologists whose principal role is microscopic evaluation of tissues⁴. This structure is also logical in that an IATP / IFSTP qualification as a capable pathologist could also lead, with a higher number of scientific publications and more academic training activities, to recognition as "Fellow" (the designation now given by the IATP). Thus, all means of global recognition as a proficient toxicologic pathologist could be efficiently administered by a single entity. Further discussion will be required to indicate whether or not the IATP and the member societies of the IFSTP concur with the position of the IFSTP Executive Committee in this regard.

What Methodology Might Be Most Suitable to Global Recognition of Proficiency?

The main issue that must be contemplated when considering a new international mechanism for identifying proficiency in pathology is the nature of the process by which recognition is to be affirmed. The two basic models to achieve this purpose are administration of a certifying examination or a review of documented credentials. Given the existing divergence in credentialing mechanisms among various national and regional societies of toxicologic pathology, the easiest avenue for developing an international recognition system in this field in the near future will most likely be recognition by credential review. However, a recognition model that simply reviews a person's self-reported record of training and experience without formally testing his or her abilities would likely be more subject to flawed decisions regarding proficiency than a system that employs a globally accepted examination covering a universally accepted body of theoretical and practical knowledge. A rigorous international examination process, supported by all the societies of toxicologic pathology and overseen by recognized toxicologic pathologists from around the world, would provide the strongest as well as the

most credible and legally defensible measure of proficiency in toxicologic pathology. Creation and administration of such an instrument would require significant resources including clear international agreement on what constitutes competency and the core body of necessary knowledge; liaison with academic bodies in different countries; many hours of professional effort by toxicologic pathologists and professional educational consultants to create and validate test questions and ways to determine fair and defensible passing scores; and considerable financial support. Other obstacles to a universal examination process are language barriers (as testing in a non-native language is difficult at best) and region-specific customs. Nevertheless, with concerted effort and consistent financial support, such an examination could conceivably be developed in 5 to 10 years.

Should such a global recognition mechanism be considered desirable by the international toxicologic pathology community, we propose that the system be fashioned with two tiers: an initial, temporary process based on credential review (i.e., does one's record of education and experience predict the likelihood of proficiency) followed some years later by an examination-based process. The greatest danger of this gradual approach is that inertia might prevent the profession from ever proceeding to the second tier. This threat may be met by affirming up front that the 1st-tier (credential review) mechanism will only be available for a finite period - ideally within five to seven years after a global recognition process is implemented. An uncomplicated means of expediting the transition would be to establish the exam-based global recognition process as a modular training program (similar to the existing BSTP system), each session of which would be followed by a test (as is done currently to qualify European Registered Toxicologists). The cycle of modules could be offered on each continent over a period of three to five years so that apprentice pathologists could train with relative convenience and little expense. Using this approach, all persons would have the same educational base (thereby affording a truly global exposure to fundamental theories and practices in the field) and undergo a comparable trial by examination (thus providing an objective means for removing cultural bias from the recognition process).

What Criteria Would Be Appropriate for Global Recognition of Proficiency?

The best benchmark for validating an individual's ability as a qualified toxicologic pathologist is repeated success in the crucible of pathology peer review. This mechanism is already utilized throughout the world, and it likely will - and should - remain the gold standard for affirming competence for years to come. Unfortunately, peer review within the context of proprietary studies is often not available for third-party review as a means of documenting competence. Furthermore, peer review per se does not automatically demonstrate proficiency, as

deficiencies which might be corrected during peer review might arise from incompetence or partial competence - including those arising because the competence of the peer reviewer cannot always be taken for granted. However, certain qualities are held in common by proficient toxicologic pathologists, and such knowledge and skills might be readily adapted to serve as criteria for an international recognition system. As outlined in the prior paper (Ettlin *et al.*, 2007 / 2008), successful practitioners will have acquired foundational knowledge in toxicologic pathology via some combination of education and on-the-job experience. The most effective educational pathway will include formal professional training in human or veterinary medicine followed by subsequent post-graduate training in pathology (often emphasizing comparative or laboratory animal pathology) and some appropriate allied discipline (generally toxicology or pharmacology). Extensive practical experience must be obtained within the academic setting and/or through an extended practicum - an apprenticeship, if you will - in applied toxicologic pathology under the tutelage of an experienced mentor. Not all components of this pathway are, however, absolute requirements. An individual who has successfully completed most or all facets of such a program should have the skills to function proficiently as an entry-level toxicologic pathologist anywhere in the world.

Any mechanism for recognizing the proficiency of a toxicologic pathologist must be tailored to a specific sub-discipline (e.g., anatomic or clinical or discovery or regulatory pathology) within the field of toxicologic pathology. With this in mind, the criteria and point system outlined in Table 1 have been formulated as a potential basis for evaluating whether or not a person would have the core knowledge and skills sufficient to render him or her qualified as a toxicologic pathologist for regulatory-type nonclinical studies in the opinion of those who must utilize his or her interpretations. In fact, the real target population of these criteria is the "bench" pathologist with at least a few years of relevant on-the-job experience - those individuals whose roles include macroscopic and microscopic evaluations of tissue morphology and integrated interpretation and communication of pathology data of regulatory-type preclinical safety studies.

The proposed list of credentialing criteria is not intended to recognize those scientists whose chief responsibilities are to conduct experiments (discovery pathologists), evaluate non-anatomic data (clinical pathologists), or manage other investigators. Should a recognition system for study pathologists be forthcoming, new criteria could be developed in the future to recognize the proficiency of these other disciplines in toxicologic pathology.

How Would the Institution Executing Global Recognition Ensure Consistent Practice Across Regions and Time?

The entity tasked with administering an international

system to recognize proficiency in toxicologic pathology must necessarily maintain unswerving standards. Given that such a mechanism must rest firmly on a globally acceptable set of pre-defined criteria, the obvious means of best guaranteeing consistent application would be to entrust recognition decisions to a single review body comprised of proficient toxicologic pathologists from throughout the world. The advantage to this approach would be that all individuals seeking recognition would be evaluated by a single board, thereby providing all applicants with a common venue for making their case. Two possible disadvantages include a potentially heavy workload placed on such a small reviewing group and the difficulty in judging candidates who practice in different cultural and regulatory settings. The authors believe that the first objection would be temporary, as any initial large number of applications would quickly clear the backlog of potential candidates and thereby lead to a much lower burden thereafter. The second disadvantage could be addressed readily in at least three ways: requiring all candidates to submit their applications in a common language and format, making global review board members from a given region responsible for first assessing the proficiency of candidates from their region, or having the global review board evaluate a certain percentage (10% to 25%) of all applications which have been forwarded by national and/or regional committees. The authors predict that either of the last two options would be more suitable means of approaching this potential disadvantage.

A corollary of any recognition process is that a proportion of existing practitioners will not meet the accepted standards for proficiency (i.e., are deemed "unqualified"). An obvious question arises with respect to their destiny. Will such individuals be suspended, or even become unemployable? We predict that such dire fates will not await these individuals, as almost all of them will be recently graduated "apprentices" gaining their initial on-the-job training in toxicologic pathology; these pathologists should in time gain the carefully supervised experience required to receive global recognition as "qualified." We anticipate that cases will be quite rare - if they ever arise at all - where a long-practicing toxicologic pathologist will be deemed unqualified and then refused global recognition if they have had regular participation in the already existing practice of regular peer review. Ideally, if a global system for recognizing quality is deemed desirable, we recommend that the credential review scheme be retired as soon as possible in favor of an examination format as such platforms are inherently more legally defensible in the face of a challenge from a disappointed candidate.

Potential Arguments Against a Formal Global System for Recognizing Proficiency

The authors wish to emphasize that the intent of this article is not to introduce an authoritative, unalterable, credentialing mechanism. Instead, the purpose is to stimulate energetic debate regarding the appropriateness of

the given characteristics and point assignments (Table 1) vis-à-vis the desired goal of recognizing that a toxicologic pathologist is proficient in critical basic areas of competence, and the desirability of implementing a worldwide recognition system. The authors recognize the difficulties and pitfalls that this proposal may face and propose to address them in the following paragraphs.

At least four arguments against establishing an international recognition system based on credential review have been raised.

- A. "Defensible certifications require formal testing." Some believe that any formal global recognition system should be based on an examination that tests both theoretical and applied knowledge rather than on mere credential review. A rigorous global examination process for competency in toxicologic pathology would be more consistent, fair, and reproducible (with some limitations) across countries, and therefore more defensible than any system based on qualitative or semi-quantitative evaluation of one's education and experience. These potential advantages must be weighed against the extent of the added benefit as well as cost, effort, and time required to implement an effective global examination process.
- B. "Suitable certifying tests already exist." Certain locales have long had or have recently instituted comparable examinations in general pathology (medical or veterinary, e.g., ACVP, ECVP, ECVCP [clinical pathology], FTA Pathol, JCVP, DESV [anatomic pathology]), or toxicologic pathology (e.g., FRCPath, JSTP). Presumably, the vast majority of experienced toxicologic pathologists would be likely to have attained accreditation from some other venue, and therefore will not require an additional form of recognition. A possible counterargument is that some examinations of this nature, especially those emphasizing local academic prejudices and/or focused broadly on general pathology, will not have sufficient breadth to serve as a global attestation of quality in the specific field of toxicologic pathology.
- C. "Credential-based recognition is too lenient." New societies of toxicologic pathology which will be forming in developing countries should be strongly encouraged - with suitable assistance from experienced colleagues in STPs from developed nations - to create curricula, apprenticeships, and certifying examinations appropriate to both the local needs and the current best worldwide practices. The primary concern is that new societies lacking sufficient resources to create and maintain a credible examination may choose to establish a relatively lax national or regional system based on credential review or pro forma testing to provide cachet to their own professionals; the recognition of marginally qualified individuals could erode the credibility of credential review, thereby defeating the point of a global recognition mechanism.
- D. "Current means of recognition are sufficient." Careful

Table 1. Proposed Criteria and Scale for Point Assignment

<div style="border: 1px solid black; padding: 10px; text-align: center;"> <i>Minimum total points required for recognition=20, at least 10 of which must come from experience (see Section 2 below)</i> Candidates must be members of an STP belonging to the IFSTP and practice toxicologic pathology as a primary responsibility </div>		
Section 1	EDUCATION AND CERTIFICATION	Max. Points Possible
1.1	Degree(s) in relevant field ^a	
1.1.1	Veterinary or medical degree or equivalent health professional degree, or license to practice such a health profession	6
1.1.2	Ph.D. or equivalent diploma in pathology, toxicology or a related field, or habilitation (P.D.) or professorship in these disciplines	4
1.1.3	M.S. or equivalent diploma in pathology, toxicology, or a related field	2
1.2	Formal recognition in pathology or toxicology	
1.2.1	Successful completion of an anatomic pathology examination ^b	4
1.2.2	Toxicologic pathology registration ^b	4
1.2.3	Completion of one toxicology examination OR Completion of toxicology registration	1
Section 2	PRACTICAL EXPERIENCE IN TOXICOLOGIC PATHOLOGY	Max. Points Possible
2.1	Postgraduate practicum in pathology or toxicology	
2.1.1	Casework in diagnostic anatomic pathology - training and service to be completed during either an accredited residency program or as a portion of an accredited graduate program in pathology at a medical or veterinary school (2 points/year for the first 2 years of casework, then 1 point/year)	5
2.1.2	Toxicologic pathology apprenticeship - documented on-the-job training in academia OR government OR industry (2 points/year for the first 2 years, then 1 point/year) ^c	5
2.1.3	Residency in toxicology, documented program at a medical or veterinary school (1 point/year)	2
2.2	Experience in toxicologic pathology ^c	
2.2.1	Practice as an anatomic pathologist for toxicology studies used to identify, investigate, register, or monitor products (2 points/year for the first 2 years, then 1 point/year)	No Limit

^a Degrees must be obtained from an accredited college or university.

^b Denotes that a maximum of 4 points can be applied if both pathology credentials (1.2.1 and 1.2.2) are held.

^c Denotes that this activity must be attested by a senior scientist who is generally accepted as a qualified toxicologic pathologist (usually an individual who has served as the candidate's supervisor and overseen at least the two most recent years of this practicum).

review of curricula for pathologists by professional institutions (e.g., private industry, regulatory bodies) is adequate, so the proposed registry does not bring value to the standard of work that is undertaken while adding a level of bureaucracy.

These concerns lead to the conclusion that any form of credentialing review should heavily over-weight an educational pathway in which a systematic medical or veterinary medical education is followed by extensive pathology practice (experience in either an established residency program or a formal on-the-job apprenticeship in pathology), the efficacy of which is then documented by

successful completion of at least one relevant examination. Thus, global recognition as a proficient toxicologic pathologist should be much more difficult to obtain if an individual follows an alternative pathway in preparing for a toxicologic pathology career.

The criteria and scale given in Table 1 have direct relevance for the arguments given above. Specific counterpoints follow here.

A. A valid counterargument to point A above is that the assignment of points in Table 1 is weighted so that recognition by credential review will not be a trivial enterprise, but rather an ordeal as demanding as any of

the existing recognition paradigms for identifying proficiency in toxicologic pathology. The organization responsible for the international recognition system will be working closely with those responsible for the national and regional accreditation pathways. Thus, the proper focus for this issue is not competition, but rather ensuring that any given recognition system will have global credibility and acceptance.

- B. With respect to point B above, the authors acknowledge the effectiveness of the existing national and regional credentialing processes used to identify proficient toxicologic pathologists. The potential credential review mechanism proposed in Table 1 is not intended to supplant the current methodology of accreditation, but rather to provide an additional means by which experienced pathologists might attain formal recognition as qualified toxicologic pathologists. A compromise which might serve to quell contentions that credential review should not be implemented at all now that many regional pathology examinations are available would be to offer credential review only for a limited transition period (i.e., until a global certifying examination in toxicologic pathology can be implemented).
- C. Regarding Point C above, it is essential that criteria for any international recognition system be applied in a consistent way worldwide. This condition necessarily requires that some supervisory body be constituted to oversee the process. The authors predict that such an entity will have an international membership and conduct its business by democratic principles.
- D. Point D may be countered by recognizing that while in a large company or regional regulatory body experienced persons will have the knowledge and network to appropriately assess/review the curricula vitae of candidates, qualified evaluators will often be lacking or be scarce in smaller institutions. In this latter situation, the value of a reliable international reference body will be large.

Conclusions: What Course Should the International Community of Toxicologic Pathologists Pursue Now?

The unrelenting pace at which globalization is progressing in general is already impacting the practice of toxicologic pathology. The authors believe that the global toxicologic pathology community will benefit if it begins now to develop common practices by which a proficient toxicologic pathologist working at the bench reviewing tissues to identify and interpret compound-induced lesions in the context of regulatory-type nonclinical studies can be rapidly and reliably identified by his or her peers - and by institutions which depend on the high quality of his or her product.

With this goal in mind, the IFSTP recommends that the international toxicologic pathology community initiate a

formal dialogue to consider the desirability and, if warranted, the means of establishing (1) global benchmarks for required core knowledge in toxicologic pathology and (2) a global mechanism by which proficiency as a toxicologic pathologist (broad general anatomic pathology specialty) might be recognized. Successful implementation of these twin objectives might be anticipated to bolster the credibility of individual members from national and regional societies of toxicologic pathology while facilitating the decision-making process at those institutions (e.g., industry, regulatory bodies, and health agencies) that depend on the high quality of scientific interpretations rendered by these professionals. The first purpose is being undertaken successfully in a gradual fashion by the continuing labors of experienced toxicologic pathologists to instruct and execute peer reviews without regard to national borders. Incremental progress toward the second goal might be achieved in the near future if due consideration of the potential recognition mechanism given in Table 1 leads to global acceptance of a workable international recognition system. Time is on our side as the existing web of national and regional certifying procedures coupled with regular peer review affords a consistent way of guaranteeing the quality of toxicologic pathology data sets across the globe. Nevertheless, a time appears to be coming when a readier means of recognizing the proficient practitioner in the field might be welcome, especially as toxicologic pathology centers which will grow in developing nations become common spots for outsourcing work in this field.

Please share in this debate by sending your comments, concerns, questions, and suggestions to the duly elected representatives of your local society of toxicologic pathology or to the editor of a toxicologic pathology journal so that your thoughts may inform the discussion. The question at hand concerns the future course of our profession. All of us must work together to find the best way forward for ourselves and our professional descendents.

Notes

- ¹ In this paper the terms 'toxicologic pathologist' and 'practitioner' - if not otherwise specified - are used for broadly trained and experienced pathologists involved in macroscopic and microscopic tissue evaluation, correlation of tissue findings with clinical pathology data, and interpretation of regulatory-type nonclinical safety studies, often under Good Laboratory Practice (GLP) rules, and generally designed according to internationally accepted standards. The output of these pathologists are reports generally of standard regulatory studies submitted to regulatory agencies around the world for marketing approval of drugs, chemicals, food components, etc. The task of these pathologists is distinctly different from that of research or academic pathologists interested in toxicities of particular organs or organ systems (their main output are often scientific publications); from clinical pathologists specializing in

analysis and interpretation of clinical chemistry, hematology, urinalysis, and the like; from pathologists engaged in other methods, such as toxicogenomics, etc.

² Current IFSTP membership includes the regional societies of toxicologic pathology representing Europe (ESTP) and North America (STP) as well as the national societies of toxicologic pathology from France (SFPT), India (STP-I), Italy (SIPTS), Japan (JSTP), the Netherlands (NVT), South Korea (KSTP), and the United Kingdom (BSTP).

³ A dedicated society recently founded in Latin America is just beginning the process of applying for IFSTP membership.

⁴ The reason for limiting the initial global recognition process for “bench” pathologists to those individuals performing macro- and microscopic evaluation of nonclinical safety studies rather than those analyzing clinical pathology data is that the first specialty is heavily used in toxicologic research settings throughout the world, while the second one (clinical pathology) is currently limited as a separate specialty to some nations / regions (Ettlin et al., 2007 / 2008).

References

- EMA (European Agency for the Evaluation of Medicinal Products), 2002. Note for guidance on carcinogenic potential. CPMP/SWP/2877/00. Last retrieved April 17, 2009, from EMA website at <http://www.emea.europa.eu/pdfs/human/swp/287700en.pdf>
- Ettlin RA, Bolon B, Pyrah I, Konishi Y, and Black HE. Global recognition of qualified toxicologic pathologists: Where we are now and where we need to go. Published in parallel [with minor variations] as *J Toxicol Pathol* 20: 267–272. 2007; *Exp Toxicol Pathol* 60: 1–8. 2008; and *Toxicol Pathol* 36: 753–759. 2008.
- FDA (United States Food and Drug Administration). 2004. Good laboratory practice for nonclinical laboratory studies. 21CFR58.29. Last retrieved April 17, 2009, from FDA website at http://edocket.access.gpo.gov/cfr_2004/aprqrtr/21cfr58.29.htm
- IATP - International Academy of Toxicologic Pathology. Last retrieved April 17, 2009, from IATP website at <http://www.iatpfellows.org/>
- IFSTP - International Federation of Societies of Toxicologic Pathologists. Last retrieved April 17, 2009, from IFSTP website at <http://ifstp.org/>
- IFSTP. Report of the IFSTP Professional Standard Subcommittee. Published in parallel as *Exp Toxicol Pathol* 55: 221–225. 2003; *J Toxicol Pathol* 16: 195–199. 2003; *Toxicol Pathol* 31: 562–565. 2003